

Subpart D—Specifically Licensed Items

§ 32.201 Serialization of nationally tracked sources.

Each licensee who manufactures a nationally tracked source after February 6, 2007 shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters.

[71 FR 65709, Nov. 8, 2006]

§ 32.210 Registration of product information.

(a) Any manufacturer or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific license may submit a request to NRC for evaluation of radiation safety information about its product and for its registration.

(b) The request for review must be sent to the NRC's Office of Nuclear Material Safety and Safeguards, Materials Safety and Inspection Branch, by an appropriate method listed in § 30.6(a) of this chapter.

(c) The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

(d) The NRC normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the NRC formulates reasonable standards and criteria with the help of the manufacturer or distributor. The NRC shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to

protect health and minimize danger to life and property.

(e) After completion of the evaluation, the Commission issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product.

(f) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with—

(1) The statements and representations, including quality control program, contained in the request; and

(2) The provisions of the registration certificate.

[52 FR 27786, July 24, 1987, as amended at 60 FR 24551, May 9, 1995; 68 FR 58805, Oct. 10, 2003]

Subpart E—Violations

§ 32.301 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of—

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of—

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186